

DEC - 1 2000

Summary of Safety and Effectiveness

3D Organ Assessment with Magnetic Position Sensing

Name and Address

Acuson Corporation
1220 Charleston Road
Mountain View, CA 94043

Contact Persons

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Common, Classification & Proprietary Names

Common:	Diagnostic Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System and Ultrasonic Transducers
Proprietary Name:	3D Organ Assessment with Magnetic Position Sensing

510(k) Number:	Unknown at this time
Date of Submission:	September 6, 2000
Predicate Devices:	TomTec's Echo-Scan and Acuson's 3D Surface Rendering (or Fetal Assessment CAP)

Device Description

The 3D Organ Assessment (OA) with Magnetic Position Sensing (MPS) is a collection of hardware and software elements. The combination of these features is a subset of the Perspective Advanced Display Option. The hardware has three main components that includes 1) a commercial MPS electronics card that plugs into a PCI slot in the 3D surface rendering option PC; 2) an MPS receiver that is clipped onto an Acuson transducer; and 3) a transmitter that is mounted at the end of a flexible arm onto a stand. This stand is connected to the 3D surface rendering option PC via an external and internal cable.

The software elements consist of two main components. The first component is the software within the ultrasound equipment which positions information from the 3D surface rendering PC, tags the image clip (frame-to-frame) with relative position information in standardized DICOM elements. The other component is the 3D

surface rendering PC that manages communications with the hardware transforms the position information and transfers the position information data to an ultrasound system on request.

Intended Use

The 3D Organ Assessment (OA) with Magnetic Position Sensing (MPS) is intended to acquire and reconstruct digital ultrasound images for computerized three-dimensional image processing. 3D OA w/ MPS will display digital clips outside of the single image plane. The MPS allows exporting to any third party application that has the appropriate level of DICOM compliance.

This software feature can be used with Acuson Aspen® and Sequoia™ Ultrasound Systems previously cleared for B-mode and Color Doppler imaging in obstetrics, gynecology, small organ, abdominal, pediatric, trans-rectal and trans-vaginal applications.

Warnings and Precautions

The addition of 3D Organ Assessment with Magnetic Position Sensing resulted in the addition of one warning related to the ultrasound system. Users are advised in additional labeling to not perform 3D OA w/ MPS on patients who wear pacemakers or defibrillators.

Potential Adverse Effects

The addition of 3D Organ Assessment with Magnetic Position Sensing did not introduce new potential hazards to the Aspen® or Sequoia™ Ultrasound Imaging Systems. Since the introduction of either systems to the ultrasound market, no adverse health effects to patient or user populations have been confirmed.

Biocompatibility

No changes of materials used in the transducers were necessary to add 3D Organ Assessment with Magnetic Position Sensing. Biocompatibility data for all Acuson transducer material contacting patients is on file.

Imaging Performance

In-house tests using test phantoms emulating an clinical environment were conducted to verify the performance of the system in B-mode imaging. Report provided in 510(k) submission.

Technological Characteristics Comparison

The Magnetic Position Sensing feature provides (relative) position tagged frames in DICOM image clips using commercially available magnetic position sensing technology in the Acuson Perspective Option. This acquisition capability is independent of any particular application (e.g., 3D reconstruction) that makes use

of the position information. Acuson's current imaging systems provide position information within the 2D scan plane, but does not provide quantitative information of the relative positions of two or more scan planes with respect to each other.

Test Discussion

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Designated technical professionals reviewed test results before software was released.

Test Conclusion

Performance specifications and design intent were met and confirmed through testing. Device performance conforms to the system performance specifications. Documentation of all performance tests will be maintained in the Device History File.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Chalon Green
Regulatory Affairs Specialist
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Mountain View, CA 94043

Re: K002807
3D Organ Assessment with Magnetic Position Sensing
Dated: September 6, 2000
Received: September 8, 2000
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO

Dear Ms. Green:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002807Device Name: 3D Organ Assessment with Magnetic Position Sensing

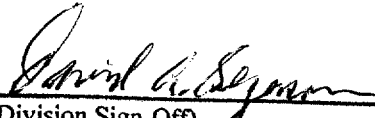
Indications For Use:

This device is an add-on option (Perspective PC) to existing Acuson Diagnostic Ultrasound Systems. The system is intended to acquire, reconstruct digital ultrasound images for computerized 3-dimensional image processing and provide quantitatively accurate multiplanar-reformatted images and 3D volume rendering for general imaging applications with the use of Magnetic Position Sensing (MPS). The system will display digital clips outside of the single image plane. The MPS will allow exporting to any third party application that has the appropriate level of DICOM compliance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use ☒

OR

Over-The-Counter Use ☐
(Division Sign-Off)Division of Reproductive, Abdominal, ENT,
and Radiological Devices510(k) Number K002807